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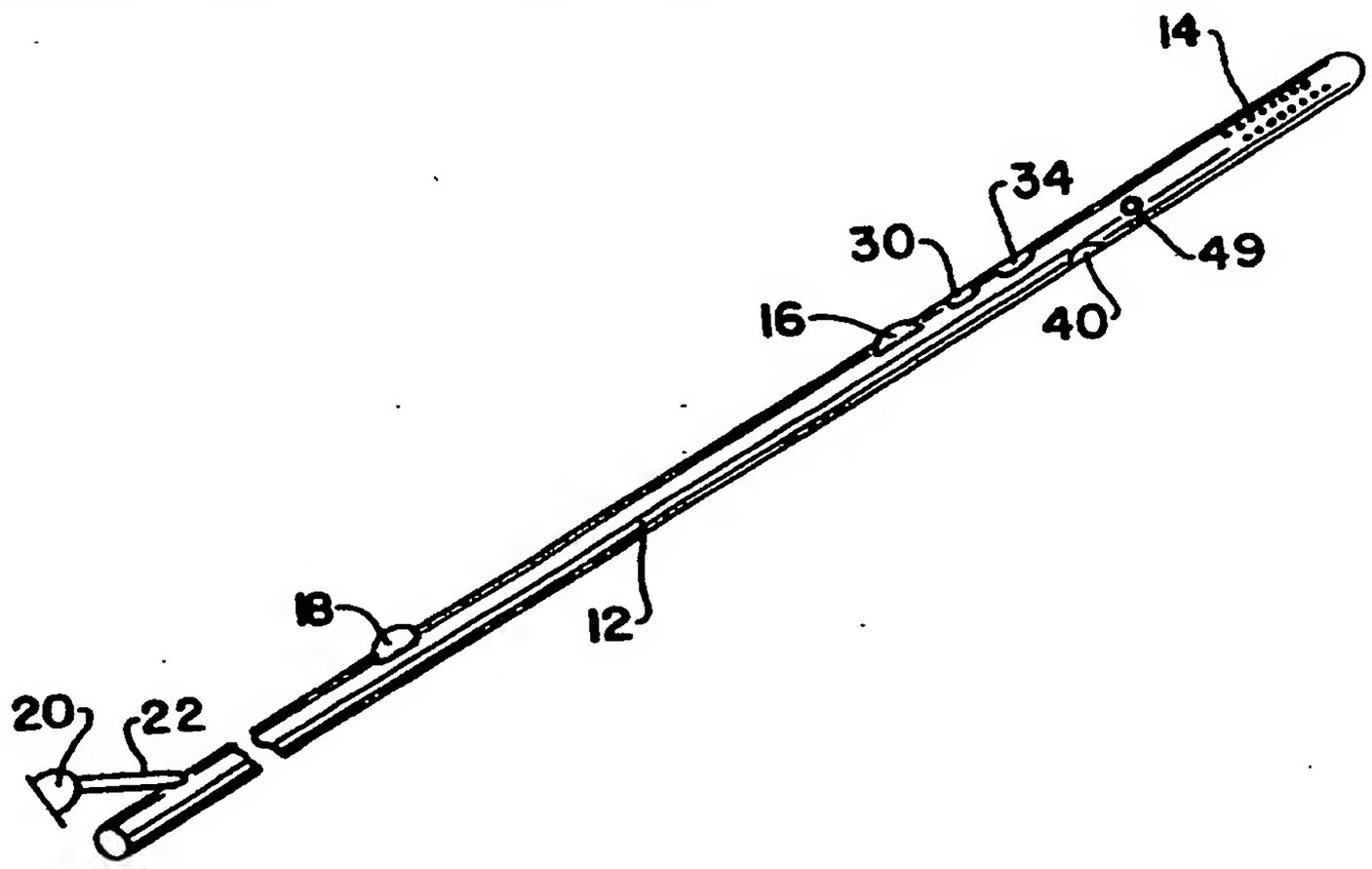
(54) Title: INFRARED OXIMETRY MEASURING DEVICE



(57) Abstract

An infrared reflectance oximetry device and method for measuring the ratio of oxygenated to deoxygenated hemoglobin within the circulation of the tissue in the brain of a subject. One embodiment is an intraventricular catheter (12) that contains an infrared oximetry source (30) and an oximetry receiver (34). A second embodiment is a bolt (106) that is screwed into the skull and mounted on the dural membrane. A third embodiment is a flexible, flat circuit board (201) which can be placed between the dural membrane and the inner table of the skull. These devices contain an infrared oximetry source and an oximetry receiver. Signals from the oximetry receiver are used to graphically represent the percentage of certain blood constituents to be measured, thus monitoring the metabolic activity of the subject.

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INFRARED OXIMETRY MEASURING DEVICE

Technical Field

The invention relates to methods and devices which are either mounted upon the dural membrane of a human brain, or within the brain itself, for measuring blood flow to the brain by infrared oximetry techniques.

Background of the Invention

Head trauma remains one of the most common causes of death and disability in the United States and Western Europe. It is responsible for an annual cost to society for hospitability, rehabilitation and job related losses exceeding 10 billion dollars; the costs in terms of human suffering are immeasurable. Current therapy directed at the management of closed head injury is based largely on empirical methods to control elevated intracranial pressure (ICP) in an attempt to preserve blood flow to the brain and reduce the likelihood of brain stroke. The effect of intracranial hypertension on cerebrovascular hemodynamics is still poorly understood. Yet there exists strong clinical and experimental data which supports the hypothesis that elevated intracranial pressure impairs the normal dilator response of cerebral arterioles to undergo compensatory dilation with elevation in arterial carbon dioxide (pCO_2). Most importantly, this vasomotor dysrequlation has been definitively linked to post-traumatic brain injury. The current therapeutic standards for reducing intracranial hypertension, namely hyperventilation and osmotic diuresis, represent areas where reduction of ICP may be gained at the cost of effective tissue perfusion and oxygenation. It is unclear whether reduction of arterial pCO_2 with concomitant arteriolar vasoconstriction provides decreased ICP without sacrificing overall cerebral perfusion and if, in fact, this may contribute to ultimate neuronal cell loss following injury. Osmotic diuresis in the presence of a compromised blood brain barrier, such as that which exists following concussive head injury, may result in extravasation of

osmotically active particles into the parencyma where they contribute to intracranial "mass effect" when normovolemia is returned. Moreover, it is not clear whether the resultant hemoconcentration afforded by such osmodiuresis impairs microcirculatory hemodynamics thereby reducing regional perfusion in the injured brain.

Recently much attention has been given to the role of ICP monitoring in the care and treatment of neurosurgical patients. The Monroe-Kellie doctrine is a physiologic expression of the relationship between ICP and cerebral perfusion. In simple terms, as pressure within the cranium rises, blood flow (perfusion) is compromised. Therefore, intracranial swelling, a common complication of central nervous system injury, can severely reduce cerebral circulation. Careful monitoring of ICP is of considerable use in treating such patients. This monitoring has been accomplished by a catheter inserted into the ventricular cavity of the brain. Measuring ICP alone does not provide all the critical physiologic data for optimal patient care. Moreover, evidence exists which demonstrates that cerebral perfusion is a dynamic physiologic process which is independent, to a great extent, of ICP.

At present, commercially available products are limited to the measurement of brain pressure. As mentioned above, reduction of ICP may be performed by the physician at the cost of reduced blood flow to the brain. Continuous monitoring of the efficiency of the blood oxygen delivery to the brain allows the physician to tailor the appropriate therapeutic regimen. Devices used to measure blood oxygen efficiency have so far been applied externally to the skull, and do not achieve desirable accuracy.

Summary of the Invention

The purpose of the present invention is to provide a method to measure accurately the efficiency of oxygen delivery to the brain by use of an infrared oximetric device

applied directly to the brain. One infrared oximetry device described is in the form of a intraventricular catheter. A second infrared oximetry device is in the form of a cylindrical carriage or bolt which is screwed into the skull and mounted directly upon the dural membrane. A third infrared oximetry device is in the form of a flexible, flat and elongated circuit board which can be placed between the dural membrane and the inner table of the skull. All three devices are invasive in nature. By "invasive" we mean that the devices are designed to be applied immediately adjacent to or inserted inside a body organ such as the brain. This may require a surgical procedure in order to gain access to the body organ. An example of such a procedure would be the drilling of an orifice or burr hole through the skull so that the invasive device may be placed next to the dural membrane or through the membrane and into the brain. The drill may be used with a drill guide as described in U.S. Patent No. 4,821,716 and Application No. 113,580, so as to allow for the controlled and properly aligned perforation of the cranium. If a catheter is to be inserted into the brain, correct placement can be facilitated by a guide assembly such as that disclosed in U.S. Patent No. 4,613,324.

The invasive device utilizes infrared technology to measure oxygenated and deoxygenated hemoglobin; and is composed of a light emitting diode source and a group of photodetectors designed to produce a signal when stimulated by light in specific ranges of the infrared spectrum. Since oxygenated and deoxygenated hemoglobin absorb infrared light in two distinct portions of the spectrum, relative reflected light of a known source intensity can be calculated to quantitatively determine the relative amounts of each infrared absorbing substance. The signal can be modified and enhanced to provide information as to the ratio of oxygenated to deoxygenated blood in the microcirculatory bed illuminated by the LED source.

Measurement of the oxygenated status of brain blood

flow allows continuous monitoring of brain oxygen extraction from the blood. At a steady brain metabolic activity rate, a drop in the oxygenated hemoglobin saturation signal would indicate increased extraction of oxygen from the blood and therefore a lower brain blood flow value. This measurement directly affects the management of a patient, for example, the patient in the intensive care unit being sustained on a respirator following brain injury. A decrease in the ratio of oxygenated to deoxygenated hemoglobin in the cerebral cortex under study would indicate a situation of inadequate perfusion, whether due to alteration in cerebral oxygen demand (a metabolic change), or alteration in cerebral blood flow.

The catheter to be inserted within the brain also may include other devices for measuring parameters of the body related to other metabolic activities. For example, the brain oximetry catheter can be combined with thermistors to measure blood flow, a pressure sensor to measure internal pressure, and an electrode for electroencephalography. In this way an assortment of body functions may be measured by the same device to ensure that the doctor can determine the proper therapeutic regimen for the patient.

By modifying and enhancing peripheral transmission oximetry, (e.g. finger) which is commercially available, with brain reflectance oximetry, the physician can judge whether the source of decrease in brain oxygenation is a cardiorespiratory or a cerebral event and take the appropriate clinical steps to address the deficit.

Brief Description of the Drawings

Other objects, features, and advantages of the invention will be seen in the following detailed description of the preferred embodiments, with reference to the accompanying drawing figures, wherein;

FIG. 1 is a perspective view of a catheter in accordance with one embodiment of the invention;

FIG. 2 is an expanded view of a portion of the catheter of FIG. 1 illustrating thermistor and oximetry devices thereon;

FIG. 3 is an expanded view of the catheter of FIG. 1 showing the relative location of drainage apertures, thermistors, oximetry devices, and pressure sensors thereon;

FIG. 4 is an axial cross sectional view of the catheter taken along the plane 4--4 of FIG. 3 illustrating the internal lumens;

FIG. 5 is a schematic illustration of the signal converter display when connected to a patient;

FIG. 6 is a schematic illustration of the oximetry bolt according to another embodiment of the invention;

FIG. 7 is an expanded view of the oximetry bolt;

FIG. 8 is the bottom view of the oximetry bolt illustrating the position of the oximetry light source and receiver;

FIG. 9 is a schematic illustration of the flexible and flat oximetry board device according to a third embodiment of the invention;

FIG. 10 is a bottom view of the flexible, flat elongated oximetry board device; and

FIG. 11 is a side view of the flexible, flat elongated oximetry board device.

Detailed Description of the Preferred Embodiments

In the first embodiment, the invention consists of a catheter 10 which is inserted into the human brain. FIG. 1 depicts an external view of the catheter 10. For ease of positioning barium markings are placed along the catheter at 4, 5, 6 and 10 cm from the tip. Catheter shaft 12 contains holes 14 for body fluid drainage. These twelve drainage holes near the distal tip are angled about 30°. from the axis of the catheter. A particularly preferred catheter design is disclosed in U.S. Patent No. 4,784,638, the disclosure of which is expressly incorporated herein by reference thereto.

In addition to the catheters which are specifically disclosed in that Patent, the present invention contemplates multi-lumen catheters of similar configuration.

Thermistor units 16 and 18 are capable of measuring the blood flow to the organ being studied using standard thermodilution techniques. The thermistor can be located anywhere along the length of the catheter that is implanted in the organ. The oximetry LED source 30 and the oximetry receiver 34 are located away from the catheter tip and 180° apart from each other on the circumference of the catheter so that direct light transmission cannot occur. Oximetry LED source 30 sends signals to oximetry receiver 34, which measures the amount of reflected light in a specific portion of the infrared spectrum representing the amount of oxygenated and deoxygenated hemoglobin. Pressure sensor 40 positioned near the catheter tip measures the pressure within the organ. Electroencephalographic electrode 49 positioned away from the catheter tip monitors electrical activity in the tissue. Cable 22 connects the wires from the electronic components in catheter tube 12 to the electric connector 20.

In operation, oximetry LED source 30, which is controlled by the signal converter 70, through wires 32, sends infrared light waves into the surrounding tissue. The light waves correspond to frequencies which are reflected from the blood constituents that are to be measured. These infrared light waves reflected from the blood constituents to be measured are detected by oximetry receiver 34. Oximetry receiver 34 creates electrical signals corresponding to the amount of each light frequency detected and sends the signals to a signal converter for display and recording via cable 22.

The catheter is inserted into the brain so as to place the oximetry LED source 30 and the electroencephalograph electrode 49 in the grey matter of the brain (cortical mantel). The oximetry receiver 34 will contact the surface of the grey matter.

FIG. 2 provides an expanded view of the thermistor unit 16. In operation, the temperature of fluid in chamber 24, when in equilibrium with the surrounding blood, is measured by thermistor 28. The measurement of the fluid temperature in equilibrium determines the temperature of the blood. In order to measure the rate of blood flow to the adjacent tissue, the fluid in chamber 24 is exchanged with a cooled fluid through tube 26. The thermistor 28 monitors the initial drop in temperature and then the subsequent increase in temperature as the cooled fluid equilibrates to the original temperature of the blood. The rate at which this equilibration occurs corresponds to the rate of blood flow to the adjacent tissue. Wires 38 run from the thermistor 28 to a signal converter where the temperature readings are converted to blood flow measurements according to the formula:

$$\text{Blood flow} = \frac{(T_{\text{blood}} - T_{\text{fluid}}) \times (\text{volume of fluid})}{\int_0^\infty T\,dt}$$

Where T represents temperature.

FIG. 3 illustrates a view partially in section of the catheter, while FIG. 4 illustrates a cross sectional view along plane 4-4. The catheter is composed of silicone, molded to a diameter of 4 millimeters and is 15 centimeters in length. The catheter is segmented into various lumens. The main lumen 42 with a diameter of 1.5 - 1.7 mm is surrounded by a .25 mm thick barium impregnated silicone wall. The inner channel of the main lumen is used for draining cerebral spinal fluid. The barium impregnated silicone wall is appropriately radio-opaque so that the position of the catheter within the brain may be monitored by x-ray. The oximetry/thermistor lumen 44 contains the oximetry source 30 and receiver 34 as well as the thermistor units 16 and 18.

The remaining lumens are used to contain various

sensors. Pressure lumen 46 contains pressure sensor 40. Electroencephalogram lumen 48 contains EEG sensor 49.

FIG. 5 illustrates the connections between the catheter 10 and the signal converter 70. The electronic components of catheter 10 have wires running into cable 22 which is terminated by end connector 20. End connector 20 fits into socket 52 which is located on signal converter 70. Signal converter 70 contains key pad 64, disk drives 62 and display screen 82. Display screen 82 displays graphs of various blood parameters denoted on FIG. 5 by 74. Socket 54 located on signal converter 70 is the connector for a peripheral oximetry device such as item 116 of FIG. 6.

The second embodiment of the invention is shown in FIGS. 6-8. Bolt 102 is screwed into the skull 200 of the patient, and mounted on the dural membrane 210 of the brain 220. Bolt 102 contains oximetry LED source 106 and oximetry receiver 108. Oximetry LED source 106 emits light of certain frequencies into the brain 220. These light waves are reflected from certain constituents of blood in the brain and are detected by oximetry receiver 108. The signal from oximetry receiver 108 is sent to signal converter 110 through wire 104. Signal converter 110 converts the signal into a desirable measurement and displays it on screen 112. The oximetry LED source is controlled by the signal converter through wire 103. Wires 103 and 104 terminate at connector 124 which fits into socket 132 located on signal converter 110.

The graph of screen 112 is compared to peripheral oximetry from peripheral oximetry device 116 which uses transmission oximetry rather than reflectance oximetry as is used by brain oximetry bolt 102. Peripheral oximetry device 116 has an LED source 120 controlled by the signal converter 110 through wire 117 and an oximetry receiver 122 which sends signals to the signal converter 110 through wire 118. The signal from the oximetry receiver 122 is converted by the signal adaptor 110 into a measurement which is displayed on

screen 114. Wires 117 and 118 terminate at connector 126 which fits into socket 134 located on signal converter 110.

FIG. 7 provides an expanded view of the bolt 102. The bolt is made of stainless steel with side torque pins 107 to facilitate the screwing of the bolt into the skull. The bottom of the bolt has 2/16 inch self tapping threads 109. The oximetry LED source 106 and oximetry receiver 108 are located at the bottom of the bolt 102 so that they may be positioned next to the dural membrane.

FIG. 8 provides a bottom view of the bolt 102 showing the oximetry LED source 106 and oximetry receiver 108 attached to ceramic microprocessor chips. The source 106 and receiver 108 are separated by an opaque wall 111 which serves as a barrier or means to prevent direct light transmission from source 106 to detector 108.

FIGS. 9-11 illustrate a third embodiment of the invention. The flat, flexible and elongated circuit board 202 is placed through a burr hole 201 of the skull 200. The light source 205 and photodetector 206 mounted at the tip of the board are placed between the dural membrane and the inner table of the skull to assure maximum contact and to measure the oxygenation of blood in the grey matter of the brain. The light source 205 and photodetector 206 are connected by cable 203 to a signal converter, a visual display screen and a data storage device which are not shown.

FIG. 10 provides an expanded top view of the flat, flexible and elongated circuit board. A light source 205, such as a LED, and a photodetector 206 are mounted on the tip of the circuit board and are connected by cable 203 to a signal converter for the measurement of the ratio of oxygenated to deoxygenated blood in the brain. The electrical connections 207 to the light source and photodetector are encapsulated by a polymer 204 to prevent fluid interference with the proper operation of the device. The light source and photodetectors themselves are also encapsulated and placed near the surface of the flexible

circuit board. The light source is mounted at an angle with respect to the photodetector so as to minimize interference in the detected signal by direct transmission of light from source 205 and thus optimize the detection of light reflected from brain tissue.

While only one light source and one photodetector are shown in FIG. 10, a number of different configurations for placing the light source and the photodetector on the tip of the probe can be made and is within the scope of the present invention. For example, a variation can be made with one light source and two photodetectors or with two light sources and two photodetectors.

While it is apparent that the invention herein disclosed is well calculated to fulfill the objects above stated, it will be appreciated that numerous modifications and embodiments may be devised by those skilled in the art, and it is intended that the appended claims cover all such modifications and embodiments as fall within the true spirit and scope of the present invention.

CLAIMS

What is claimed is:

1. An invasive spectrophotometric device for measuring the metabolic activity of an organ of a subject comprising:

a support structure in direct contact with the organ of the subject;

means mounted upon the support structure in contact with the organ for generating one or more frequencies of light toward said the organ; and

means mounted upon the support structure for collecting light reflected from the organ and for detecting light frequencies corresponding to a specific stage of metabolic activity of the organ;

wherein the light generating means cannot directly transmit light to the light detecting and collecting means.

2. The device of claim 1 wherein the support structure is a catheter, the forward end of which contains a plurality of spaced apertures extending through the catheter wall at an angle such that a portion of the catheter wall is visible when viewing the apertures perpendicular to the axis of the catheter body, whereby the position and configuration of the apertures minimizes or prevents tissue growth thereinto.

3. The device of claim 2 wherein the organ is the brain, the catheter includes means for measuring one or more of blood flow, internal pressure and electrical activity in the brain, and the catheter is inserted into the ventricle of the brain.

4. The device of claim 1 wherein the organ is the brain and the support structure is a generally cylindrical member which is mounted in an aperture in the skull of the subject in contact with the brain for monitoring a specific state of metabolic activity therein.

5. The device of claim 1 further comprising means for transmitting the detection of reflected light to a signal converter capable of providing a substantially continuous and rapid measure of the metabolic activity.

6. The device of claim 1 wherein the organ is the brain and the metabolic activity is brain oxygen extraction from the blood; and wherein the means for generating light is a LED source capable of emitting a light spectrum which includes one frequency selectively absorbed by oxygenated blood and a second frequency selectively absorbed by deoxygenated blood.

7. The device of claim 6 wherein the signal converter can provide information as to the ratio of oxygenated to deoxygenated blood in the portion of the brain which is illuminated by the light generating source.

8. The device of claim 7 which further comprises means for storing the data from the signal convertor.

9. The device of claim 1 wherein the means of collecting the reflected light comprises one or more photodetectors.

10. The device of claim 1 further comprising noninvasive means for measuring metabolic activity of said brain, wherein the invasive measurement of metabolic

activity of the brain is compared to the noninvasive measurement of metabolic activity of the brain so as to determine whether the degree of the metabolic activity is occurring locally or throughout the body of the subject.

11. The device of claim 1 wherein the support structure is a flat, elongated member having the light generating means and the light detecting and collecting means is located at the forward end thereof.

12. The device of claim 11 wherein the flat, elongated member is a flexible circuit board which is encapsulated by a polymer to prevent fluid interference with the circuits thereon, wherein the means for generating light is a LED source capable of emitting a light spectrum which includes one frequency selectively absorbed by oxygenated blood and a second frequency selectively absorbed by deoxygenated blood, and wherein the means for detecting and collecting reflected light comprises one or more photodetectors.

13. The device of claim 12 wherein the LED source is mounted upon the circuit board at an angle with respect to the photodetector to minimize interference and optimize the detection and collection of reflected light.

14. The device of claim 1 which further comprises barrier means to prevent the direct transmission of light from the light generating means to the light detecting means.

15. A method for invasively measuring local metabolism of a body organ such as the brain, which comprises:

contacting a body organ with a spectrophotometric device comprising a support structure, means mounted upon the support structure in contact with the organ for generating one or more frequencies of light thereto, and means mounted upon the support structure in contact with the organ for collecting light reflected from the organ and detecting light frequencies corresponding to a specific stage of metabolic activity thereof, whereby the light generating means cannot directly transmit light to the light detecting means;

directing predetermined light frequencies to the organ;

collecting light which has been reflected from the organ; and

detecting reflected light frequencies corresponding to a specific stage of metabolic activity of the organ.

16. The method of claim 15 wherein the organ is the brain and wherein the accessing step includes drilling an orifice through the skull prior to contacting the brain with the invasive spectrophotometric device.

17. The method of claim 16 wherein the spectrophotometric device includes a catheter and wherein the contacting step includes directing the catheter through the the orifice, through the dural membrane and into a ventricle of the brain.

18. The method of claim 16 wherein the spectrophotometric device includes a cylindrical carriage and wherein the brain contacting step includes screwing the carriage into the orifice so that a lower portion of the carriage contacts the dural membrane of the brain.

19. The method of claim 16 wherein the spectrophotometric devices includes a flexible, flat, elongated circuit board and wherein the contacting step includes inserting the circuit board into the orifice at an angle to place the circuit board between the skull and the dural membrane of the brain.

20. The method of claim 15 wherein the measurement of the metabolic activity of the organ is enhanced by conducting peripheral, non-invasive transmission oximetry on a portion of the body of the subject, and which further includes displaying the invasive and non-invasive oximetry measurements for analysis thereof.

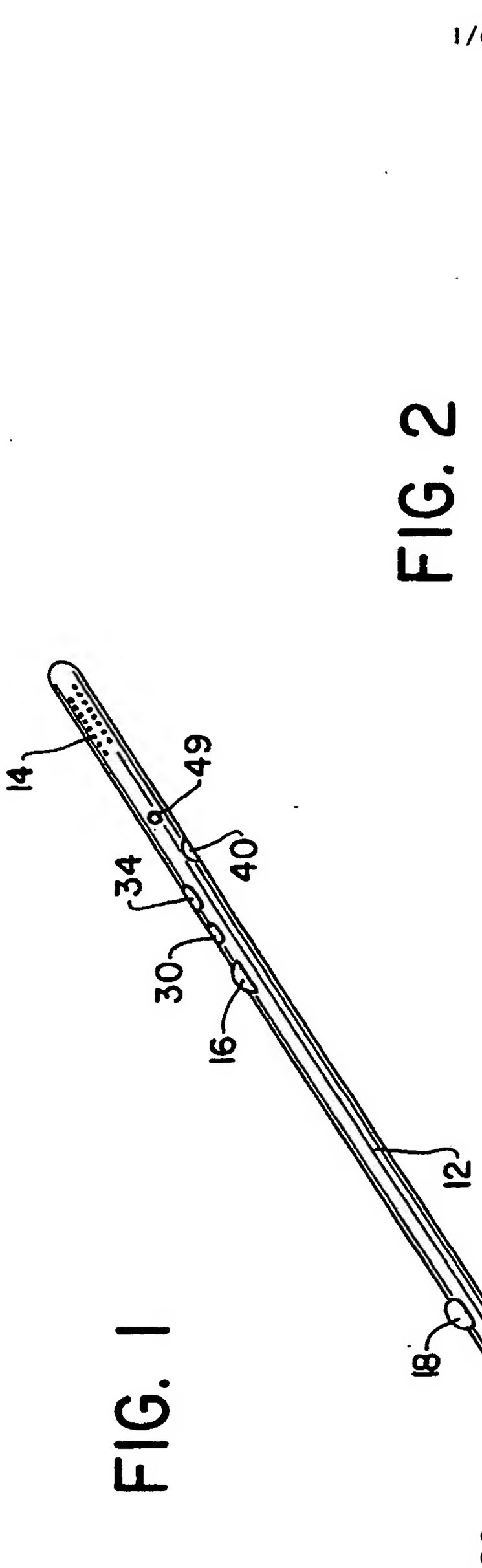


FIG. 1

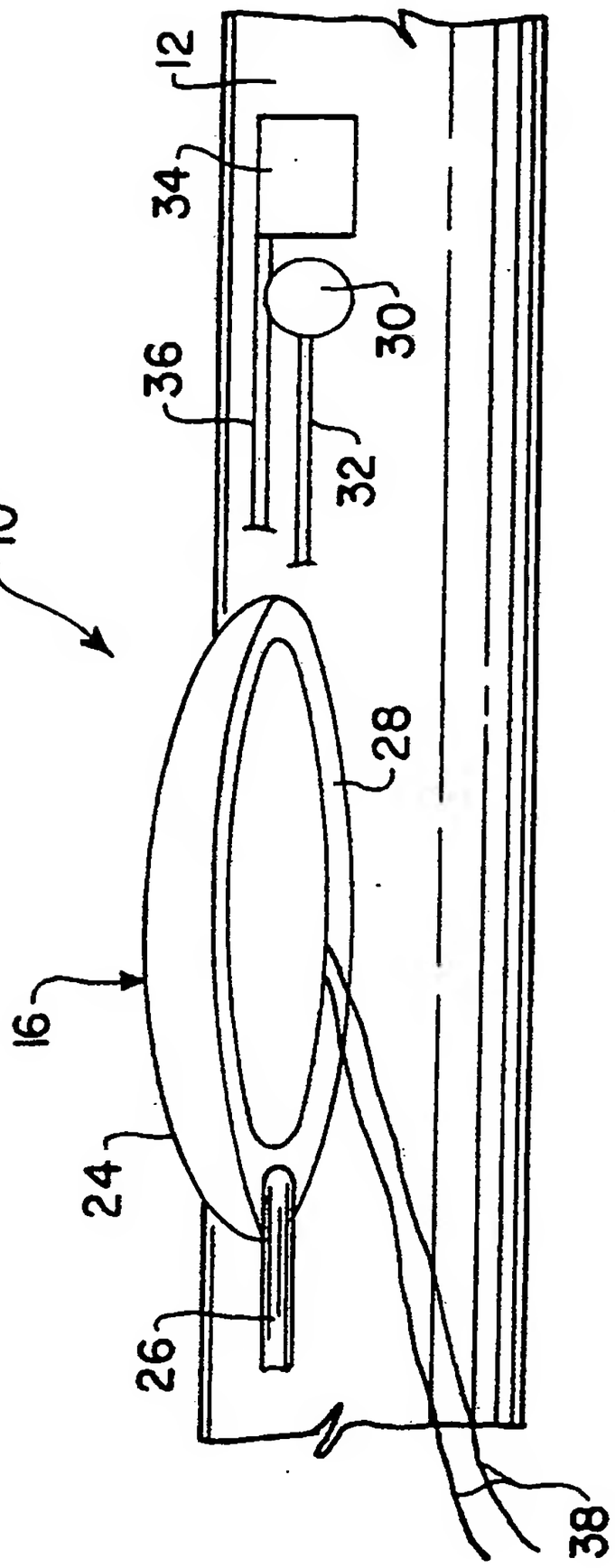


FIG. 2

FIG. 3

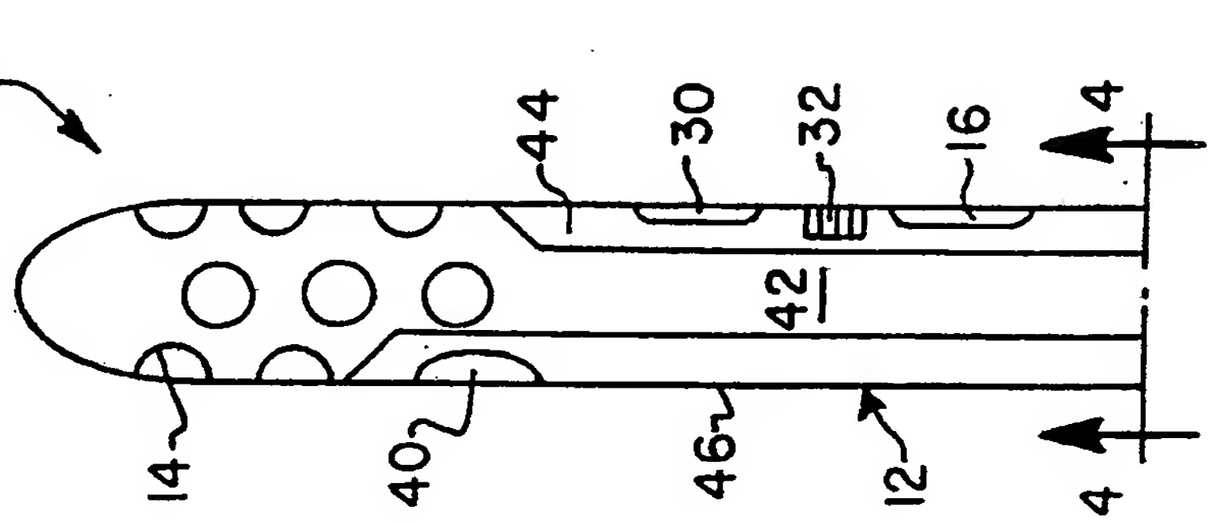


FIG. 4

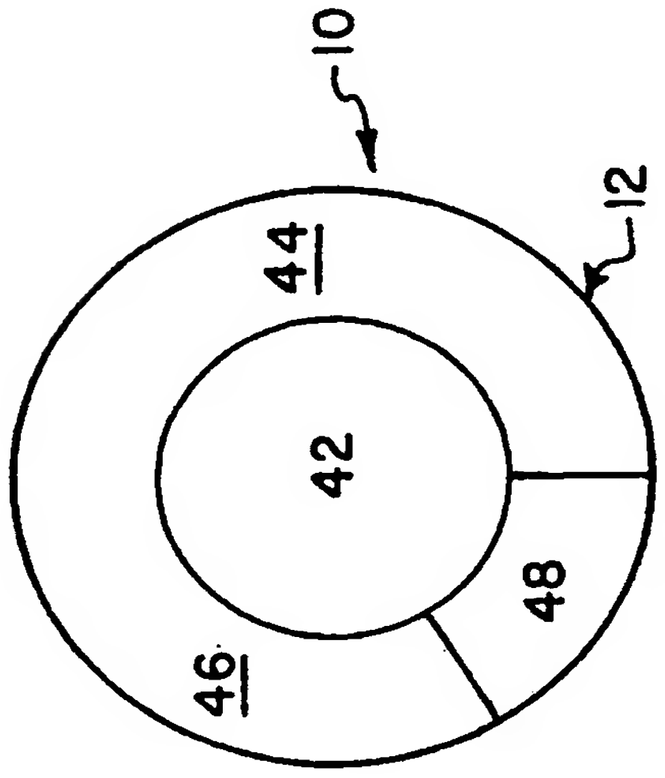
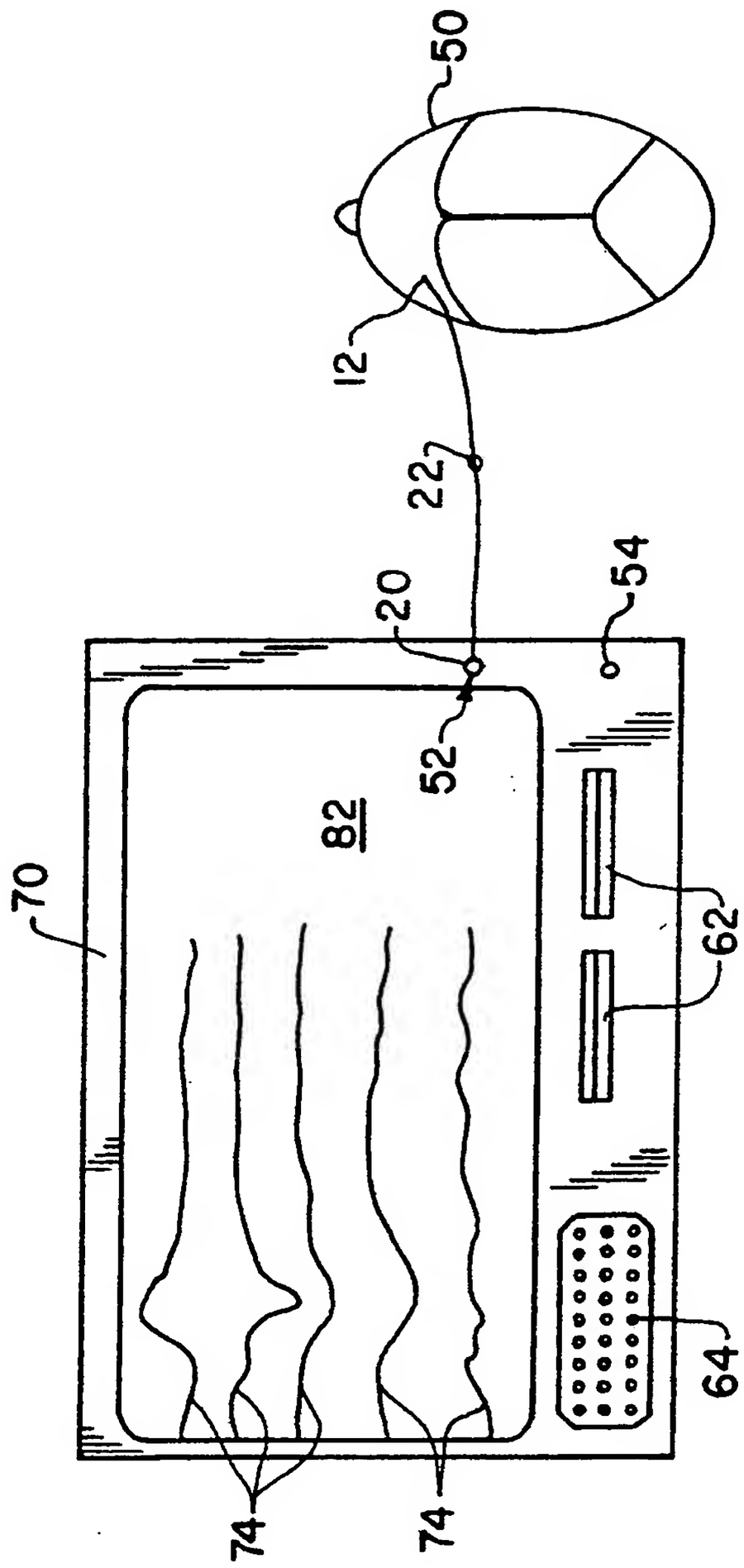


FIG. 5



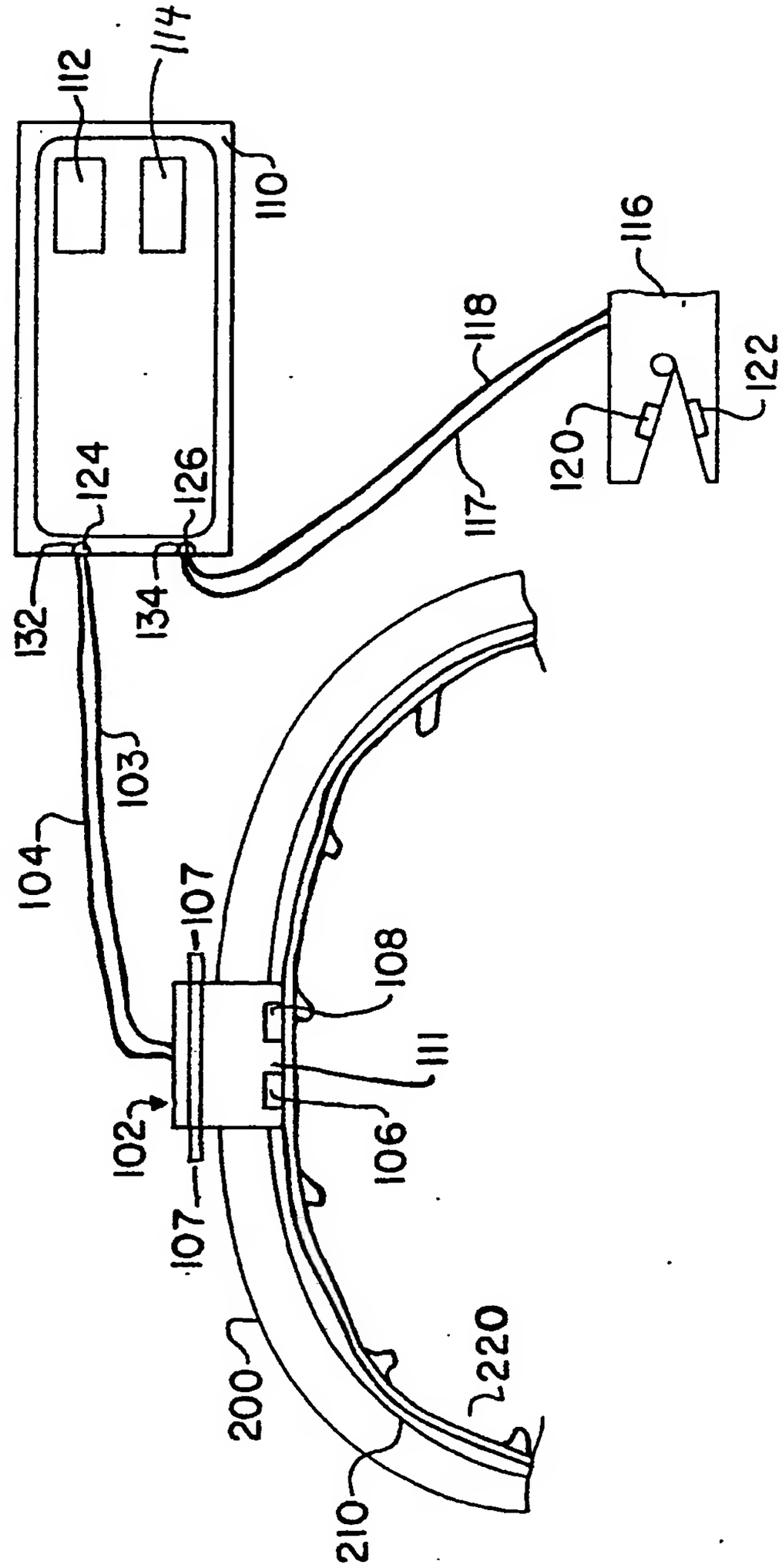

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FIG. 6

FIG. 7

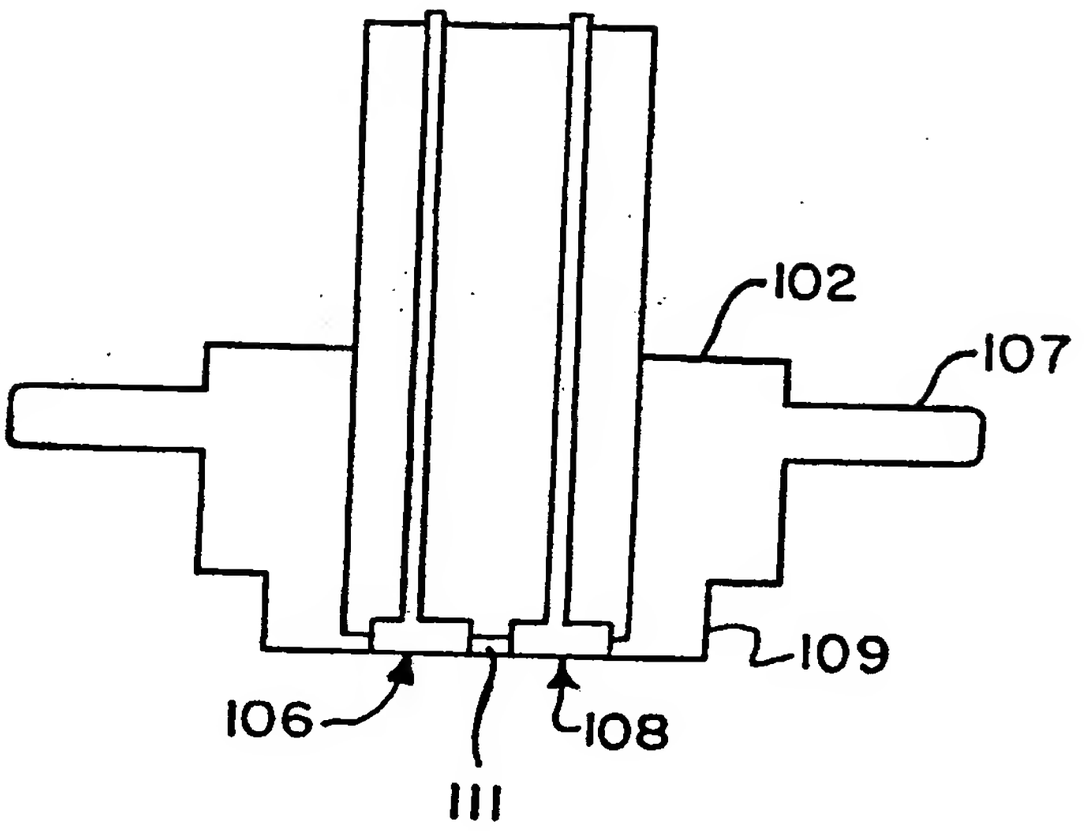
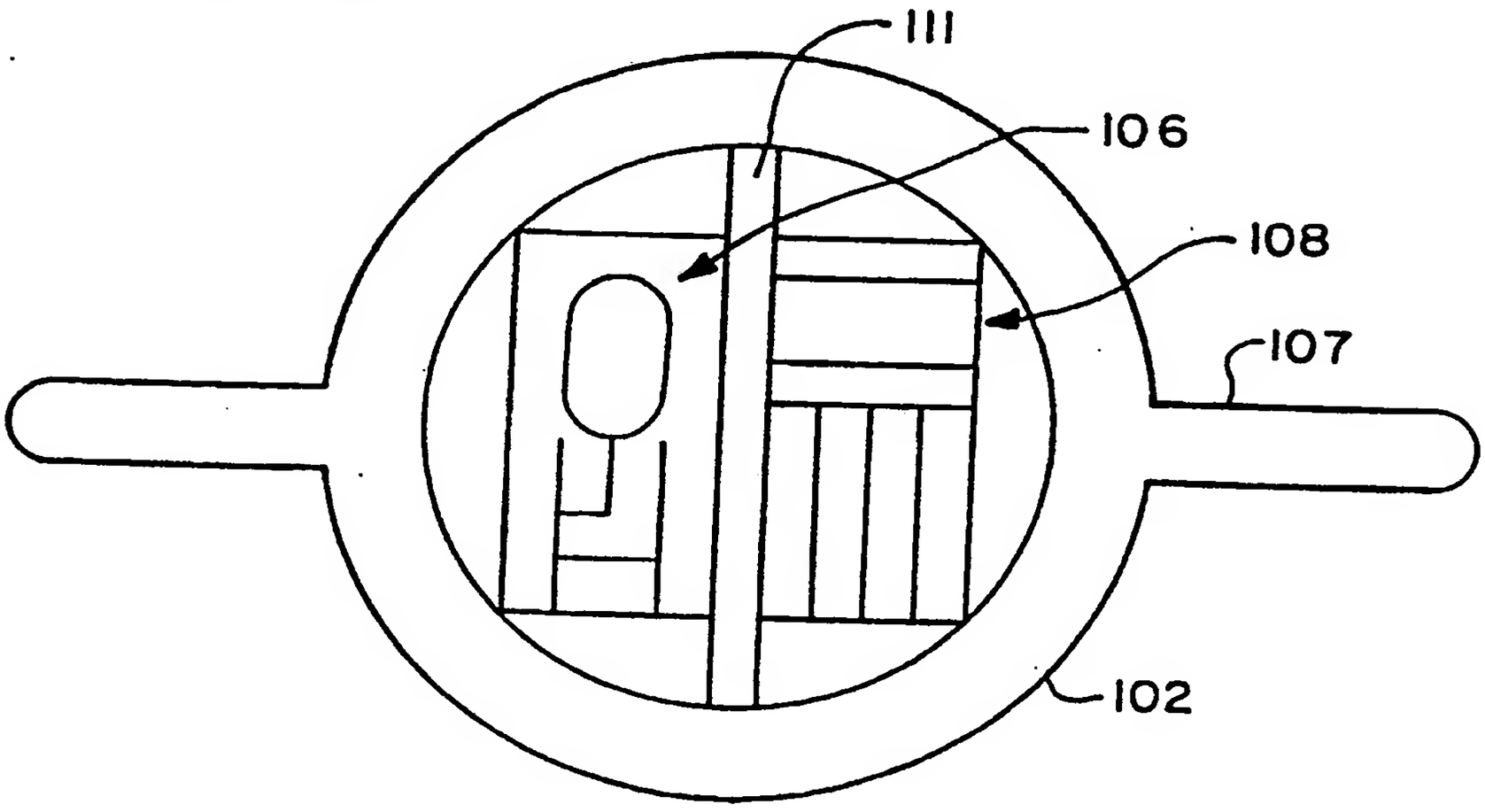


FIG. 8



INTERNATIONAL SEARCH REPORT

International Application No. PCT/US90/00181

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5) A61b 10/00; A61b 17/00; A61m 25/00
US 128/633, 736,691,748

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
US	128/632-634,637,639,642,653,664-666, 670,691, 731, 736, 748

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X / Y	US, A, 4,700,708 (NEW) 20 October 1987 See entire document	1,5,10,12 / 4,7,9,11,13-20
X / Y	US, A, 4,223,680 (JÖBSIS) 23 September 1980 See entire document	1,5,6,8 / 2,3,4
Y	US, A, 4,739,771 (MANWARING) 26 April 1988 See entire document	2,3,17-20
Y	US, A, 4,485,820 (FLOWER) 04 December 1984 See entire document	7,9,14-20
Y	US, A, 3,796,213 (STEPHENS) 12 March 1974 See entire document	11
Y	US, A, 3,605,726 (WILLIAMS) 20 September 1988 See entire document	13
Y	US, A, 4,784,150 (VOORHIES) 15 November 1988 See entire document	16
Y	Medical Instrumentation, Vol. 16, No. 4, July-August, 1982 (MORTARA) "Intracranial Pressure Monitoring in the Emergency Setting," 2 pages	4,18

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
26 MARCH 1990	19 APR 1990
International Searching Authority	**Signature of Authorized Officer**
RO/US	DAVID SHAY

Form PCT/ISA/210 (second sheet) (Rev.11-87)